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1 A. The answer is: It's simple, but it's risky.

2 Okay? I hope that answers -- I'm not trying to be  
3 evasive.

4 Q. Go back, at the very end of the Introduction  
5 section. You are talking about your walk-through at  
6 Actavis --

7 A. Right.

8 Q. -- this year. It says, "During this  
9 inspection, all the equipment and related questions as  
10 related to the equipment were adequately addressed  
11 with no open issues."

12 A. Right.

13 Q. What do you mean by "no open issues"?

14 A. Everything I asked to see, I was able to see.  
15 Any questions I had were answered. Nothing was left  
16 open.

17 Q. Got you.

18 A. I was satisfied when I walked out.

19 Q. All right. Let's go to Page 4, please.

20 At the top, underneath the formula for  
21 Digitek --

22 A. Right.

23 Q. -- you are talking about "the amount of  
24 digoxin to be used in the batch is corrected."

25 A. Uh-huh.

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1 Q. Etc., etc. Do you see that paragraph?

2 A. Yes.

3 Q. Are you talking about Batch 70924  
4 specifically there?

5 A. Although 7029 -- 70924 is an example, I found  
6 that in the batch records I had, this is a common  
7 practice.

8 Q. All right. Well, that was a bad question.

9 Because what I really want to ask you about  
10 is the last sentence there. It says, "The blending  
11 process did not show any procedural issues or  
12 unexpected deviations from the established directions  
13 and planned deviations as set in place."

14 Do you see that?

15 A. Yeah.

16 Q. In that sentence, are you referring to 70924?

17 A. Yes, sir.

18 Q. In short, it appeared appropriately blended?

19 A. Absolutely, based on the information I  
20 reviewed.

21 Q. All right. Then in the next paragraph, you  
22 are talking about the blend sampling?

23 A. Yes, sir.

24 Q. And you talk about how they're withdrawn from  
25 the blender using a sampling feed.

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1 A. Right.

2 Q. And you comment on that. And that's  
3 appropriate; right?

4 A. Yeah.

5 (A discussion is held off the record.)

6 Q. "Three sets of samples are taken to assure  
7 material is available should a repeat blend test be  
8 required."

9 Is that what you wrote?

10 A. That's exactly what I wrote.

11 Q. Is it appropriate to do that?

12 A. As we discussed this morning, yes, Matt, it  
13 is.

14 Q. All right.

15 A. And it's also in the guidance.

16 Q. Let's go to the next page. The question on  
17 tabletting.

18 A. Yes, sir.

19 Q. I'd say we can skip that. We covered that  
20 before.

21 A. Yeah.

22 Q. Let's go to Page 7, please.

23 A. Right.

24 Q. Under Investigation Report, the second  
25 paragraph.

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1 A. Right.

2 Q. "The investigation report goes on to note  
3 that a potential root cause for the occurrence of the  
4 thick tablets may be an artifact of the compression  
5 machine start-up procedure."

6 Do you see that?

7 A. Yes, sir.

8 Q. And then you say, "This is credible."

9 What do you mean by that?

10 A. That it makes perfect sense to me.

11 Q. Does that happen in start-up in tabletting?

12 A. It happens with start-up all the time, Matt;  
13 yes, sir.

14 Q. Is that why you discard the first start-up  
15 tablets, because they can be out of spec?

16 A. That's why you pull away the equipment, you  
17 put reject buckets under it to discard it, right.

18 Q. Now, based on the number of times that my  
19 client's press operators went through the start-up  
20 process for this particular batch, did you make any  
21 attempt to estimate the number of tablets that would  
22 be produced during the start-up process?

23 A. No, I didn't.

24 Q. And you later comment in the next paragraph  
25 that a problem could occur if these oversized tablets

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1 made during start-up got hung up in a deduster or  
2 metal detector; right?

3 A. That's correct.

4 Q. And have you seen that happen in your own --

5 A. Yes.

6 Q. -- work in the pharmaceutical --

7 A. Yes, I have.

8 Q. -- business?

9 A. And my walk-through assured me that the  
10 equipment used by Actavis, the likelihood that that  
11 happens is small; very visible, very, very easy to  
12 verify.

13 Q. All right. All right.

14 We're running out of time on the tape, so as  
15 much as I don't like to do it, we need to take a  
16 break.

17 A. Sounds good to me.

18 THE VIDEOGRAPHER: Stand by. We are going off  
19 the record. The time is 2:54 p.m. This is the end  
20 of Tape Number 4.

21 (A recess is taken.)

22

23 CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

24 THE VIDEOGRAPHER: We are back on the record.

25 The time is 3:09 p.m. This is the beginning of

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1 Tape Number 5.

2 Q. Dr. Somma, I was asking you some questions  
3 about your report.

4 A. Yes, sir.

5 Q. So let's go to Page 8.

6 A. Yes, sir.

7 Q. Now, so far as Batch 70924A is concerned, you  
8 are aware that my client, when it finished all of its  
9 inspections on that batch, found a total of 20  
10 double-thick tablets. Is that right?

11 A. That's my understanding, yes, sir.

12 Q. Okay. Do you have an opinion to a reasonable  
13 degree of probability as to whether or not my client,  
14 in its inspection of that batch, failed to detect any  
15 other extra-thick tablets?

16 A. In my experience, we never relied on a visual  
17 inspection to release a batch.

18 Q. Sir.

19 A. I didn't answer the question.

20 Q. You didn't.

21 A. No.

22 MR. MORIARTY: Can you read that question  
23 back, please?

24 Q. It was a very specific question.

25 (The question is read.)

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1 MR. MILLER: Objection. Asked and answered.

2 A. Okay. I don't -- the probability is they did  
3 not detect all of them.

4 Q. Do you have an opinion to a probability as to  
5 how many were made that were extra thick that were not  
6 detected?

7 A. I don't have a hard and fast rule, but my  
8 rule of thumb was if you see 20, you got a thousand.  
9 That's just Russ Somma's rule. Opinion, that's all.

10 Q. And Russ Somma's rule, is it based on  
11 controlled trials where you tried visual inspections  
12 and tried to see how many were caught or missed?

13 A. It's based on my experience in scale-up of  
14 processing. It has never been confirmed by taking  
15 them out and measuring if my rule is correct.

16 Q. Is it based on peer-reviewed literature?

17 A. No.

18 (A discussion is held off the record.)

19 Q. So it's not based on actual scientific  
20 studies where you compared visual inspections'  
21 accuracy to actual defect rates?

22 A. No, Matt, it's not.

23 Q. So I want to get back to my question.

24 Do you have an opinion to a probability as to  
25 how many extra-thick tablets were made but not caught

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1 during the inspection of 70924?

2 MR. MILLER: Objection. Asked and answered.

3 A. It's hard for me to say, so I would have to  
4 say the probability is high that there would be more.

5 Q. But you can't give me to a probability a  
6 number?

7 A. A number, no, sir.

8 Q. So 70924 is then bottled; correct? Do you  
9 have an opinion to a probability as to whether there  
10 were extra-thick tablets in every bottle?

11 A. That would assume a uniform distribution  
12 across the batch. I can't say yes or no; however, I  
13 think the prudent approach was to dump them back and  
14 inspect again, which they did, yes.

15 Q. I understand that. I'm talking about after  
16 the inspection.

17 A. Oh.

18 Q. You are saying you think there were still  
19 extra-thick tablets that my client did not detect;  
20 right?

21 A. That's right.

22 Q. And you have no actual basis for that other  
23 than your experience --

24 A. My experience.

25 Q. -- that visual inspection is not that

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1 accurate; correct?

2 A. That's correct, sir.

3 Q. Now, my client, after the inspection, 100  
4 percent inspection and after the tight AQL, repackaged  
5 the batch; did it not?

6 A. Yes. They did.

7 Q. Into bottles; right?

8 A. Yeah, uh-huh.

9 Q. Do you have an opinion to a reasonable degree  
10 of probability as to whether there were defective  
11 tablets in all the bottles?

12 A. There were certainly defective tablets there  
13 that would not be detected. Would they be in all the  
14 bottles? I don't know.

15 Q. Do you have any opinion to a probability as  
16 to how many of those tablets that may have been  
17 defective actually made it into the prescription of a  
18 consumer?

19 (A discussion is held off the record.)

20 A. I didn't look at the field complaints, so I  
21 don't know. You know, that would be how I should have  
22 done it. I did not do that.

23 (A discussion is held off the record.)

24 Q. Well, the field complaints, unless the  
25 consumer got it and said, "this is a double-thick

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1 tablet," the field complaint wouldn't necessarily tell  
2 you anything?

3 A. Exactly.

4 MR. MILLER: Object to form.

5 A. Exactly.

6 Q. So it is at least conceivable that if any  
7 extra-thick tablets got out, the number of which we  
8 don't know, it may have been a return to stericycle in  
9 the process of the recall. Correct?

10 A. I think that's a reasonable thought, yes.

11 Q. Do you have any basis at all to say that  
12 extra-thick tablets were made in the batch that was  
13 made before 70924?

14 A. No, sir.

15 MS. CARTER: Object to form.

16 Q. Do you have any basis in any of the material  
17 you have reviewed to say that there were extra-thick  
18 tablets made in the batch after 70924?

19 MS. CARTER: Object to form.

20 A. I think the only -- my only -- my only basis  
21 would be that they did not do a thorough enough  
22 investigation on the thick batch itself. That's the  
23 only thing. Did I see anything else? No.

24 Q. Would you concede that it is possible that  
25 the 100 percent inspection did get all of the

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1 extra-thick tablets out of 70924 before it went to  
2 market?

3 MR. MILLER: Object to form.

4 A. In my opinion, it could not happen.

5 Q. It's impossible?

6 A. It's impossible.

7 Q. Have you got any basis for that?

8 A. Yeah, human fatigue. That's why we have  
9 vision systems for inspection. It's a fact.

10 Q. Well, how many -- how many people performed  
11 the 100 percent inspection?

12 A. Well, customarily you don't do 100 percent  
13 inspection unless it's part of your process.

14 Q. Dr. Somma, there is an actual document that  
15 talks about how many people did this inspection and  
16 how many days it took them to do it.

17 A. Right.

18 Q. How many people did the 100 percent  
19 inspection?

20 A. I don't recall. I'd have to guess.

21 Q. How many -- how many days did it take them to  
22 do it?

23 A. I don't recall.

24 Q. Go to the second paragraph on Page 8.

25 A. Right.

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1 Q. Is it possible that the extra-thick tablets  
2 were within the API specifications?

3 A. It's very probable. Or very possible.  
4 Excuse me. It's possible, yes. We don't know what  
5 they were made out of, so possible.

6 Q. Third paragraph.

7 A. Right.

8 Q. The second sentence.

9 A. Right.

10 Q. Can you tell me what that means?

11 A. "Recorded observations when considered  
12 against the theory that such a tablet would have been  
13 randomly produced during the normal manufacture of  
14 tablets is without merit."

15 Meaning: In my opinion that this just  
16 wouldn't happen sporadically based on what I had seen.  
17 The -- you know, simply based on observations  
18 contained in the records.

19 Q. So if I understand what you are then saying  
20 --

21 A. Right.

22 Q. -- after that, it lends credibility to the  
23 theory that the start-up is the more likely time when  
24 double-thick tablets were produced?

25 A. I think, based on the evidence that I've

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1 looked at, yes, sir. It gets back to that.

2 Q. Is that the most likely cause of what  
3 happened, in hindsight?

4 A. It certainly is one of the things I look to  
5 go to after I do an investigation -- a review of the  
6 batch records.

7 Q. Have you formed an opinion to a probability  
8 about what the root cause of the double-thick tablets  
9 in 70924 was?

10 A. My -- my opinion is the probability is about  
11 50 percent that that is a result of start-up and  
12 shutdown of a piece of equipment.

13 Q. So it's 50-50?

14 A. 50-50.

15 Q. That's actually a possibility; correct?

16 A. A possibility.

17 Q. What are the other possibilities?

18 A. We go on to talk about a few of them, where  
19 the tablet itself would have adhered to the punch and  
20 rode around and back in and re compressed.

21 Q. Yeah, but you said that was unlikely --

22 A. Unlikely.

23 Q. -- in our experience.

24 A. Right.

25 Q. So that's not probable?

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1 A. That's unlikely.

2 MR. MILLER: Object. Object to form.

3 Q. Isn't "unlikely" not probable?

4 MR. MILLER: Right, but you are asking for the  
5 remaining 50 percent, so...

6 Q. I haven't asked anything about the remaining  
7 50 percent. This is one question at a time here.

8 MR. MILLER: Well, object to form.

9 A. My apologies for my selection of words. I  
10 find that possible, but not probable.

11 Q. Okay.

12 A. Okay? Does that help?

13 Q. Yes. That's the recompression?

14 A. Right. The --

15 Q. And you -- and you said up here that  
16 "randomly producing them during normal manufacture is  
17 without merit;" correct?

18 A. That is correct.

19 Q. And would not support random compression?

20 A. Right.

21 Q. So isn't that unlikely?

22 A. That is -- that's unlikely.

23 Q. All right. Do we have any other explanations  
24 that compete with start-up for the likely explanation?

25 A. Nothing that I would be able to come up with

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1 other than -- yeah, other than complete speculation.

2 Q. And certainly in a -- what is this, a  
3 45-station tablet press?

4 A. 45 station, double sided, yes.

5 Q. So it's 90 tablets at start-up per  
6 revolution?

7 A. That's right.

8 Q. Per press?

9 A. Right, there's two presses.

10 Q. So even if they only had one revolution per  
11 press at start-up, you are talking about 180 tablets;  
12 right?

13 MR. MILLER: Object to form.

14 A. Yeah, I -- I'd go with that.

15 Q. Okay.

16 A. Matt, I'd even say -- even if it is twice  
17 that amount. Because remember, this thing can move  
18 around. Let's just say it's -- say it's 180 exactly.  
19 All right?

20 Q. Let me just stick with the number of 180  
21 tablets --

22 A. Okay.

23 Q. -- to keep my life simple here.

24 A. All right.

25 Q. Is it likely that my client's inspection

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1 missed 160 extra-thick tablets in that batch?

2 A. It's possible.

3 Q. I asked if it was likely.

4 A. Likely?

5 Q. Yes.

6 A. I think it's likely.

7 Q. Okay. Is it likely they missed 360?

8 A. Wouldn't possible -- all 360? I can't -- as  
9 the number grows, I think it becomes more apparent;  
10 but --

11 Q. I'm asking a specific number. Isn't it  
12 unlikely that that many people inspecting over that  
13 amount of time with a product they're familiar with  
14 would miss that many?

15 MS. CARTER: Objection to form.

16 A. As the number grows, it becomes less likely;  
17 right.

18 Q. Well, the number grew from 180 to 360. It's  
19 already unlikely that they missed that many; isn't  
20 that right?

21 A. I would have to agree that they would miss  
22 all of them? No way.

23 Q. Let's go to Page 11 of your report.

24 A. Uh-huh, got it.

25 Q. On the second paragraph on that page, please.

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1 A. Okay. This means?

2 Q. "This means that the drug or API used for the  
3 product must be well-characterized and understood."

4 Do you see that?

5 A. Yes, sir.

6 Q. "We did not see any data that indicated the  
7 firm did any physio --"

8 A. Physicochemical.

9 Q. "-- physicochemical review of the drug in  
10 problem batches."

11 First of all, what batches are you talking  
12 about?

13 A. In this particular case, and I apologize that  
14 it's not clearer, by "problem batches" I meant the  
15 two -- the batches that I looked at. One was that  
16 batch that had the blend issue, and the other was  
17 the -- the double thick tablet. That was the problem  
18 batches I've talk about.

19 And the comment to get to is simply that I  
20 didn't see the -- customarily in my experience, the  
21 culprit is usually the API, and you do a little more  
22 looking at the API.

23 Q. Which blend batch are you talking about?

24 A. Again, this gets back to the batch I looked  
25 at.

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1 Q. Yeah, I want to know which one it is?

2 A. That's 71 -- 710 -- the other one I looked  
3 at, which is 71005.

4 Q. 71005? Do you have Batch Record 71005 with  
5 you?

6 A. Yeah, I do. It's right here. And the thing  
7 I'm looking at is there is an OOS investigation tag on  
8 the back; okay?

9 Q. Do you know whether 71005 was released?

10 A. I should be able to look here; right?

11 Q. To market.

12 A. I have a finished product release form. I  
13 guess it was.

14 Q. Okay. That's a 0.125 batch?

15 A. Yeah, yes, sir. Yes it is, yeah.

16 Q. And what do you mean by a physicochemical?

17 A. Customarily what we want to look at is that  
18 API itself is behaving as it was. These things have a  
19 tendency to drift in properties: Physical appearance,  
20 morphology, things like that.

21 It's something Actavis would have to do to  
22 monitor the guys selling the stuff to them. Okay?  
23 It's sort of a control of your supply chain.

24 Q. Do you know whether they test every batch of  
25 active pharmaceutical ingredient that they receive?

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1       A. I looked at the ANDA for Digitek, and it was  
2 clear to me that they tested all the incoming batches  
3 based on the ANDA. All incoming batches of API.

4       Q. Okay.

5       A. Right.

6       Q. So is that the kind of physicochemical review  
7 you are talking about?

8       A. No, Matt. It usually goes a little bit  
9 beyond that, and they did do that. I've seen evidence  
10 of particle size determination by a Malvern  
11 synthesizer when I did my walk through. But there's  
12 other things you look at: Thermochemistry,  
13 morphology, searching things under a microscope.

14                     (A discussion is held off the record.)

15       A. This is stuff that I customarily look at when  
16 I'm doing such an investigation.

17       Q. Okay. I want to get back to something I was  
18 asking you before, because I forgot something. And  
19 I'm sorry if I'm repeating anything I went over this  
20 morning.

21                     I asked you whether you had any basis to say  
22 that there were thick tablets made or released in the  
23 batches before and after 70924. Do you remember that  
24 question?

25       A. Yes, sir.

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1           Q. All right. Do you have any basis to say that  
2 there were extra-thick tablets made and released to  
3 market in any other Digitek batch in 2005 or after?

4           A. Without having the root cause in front of us,  
5 I would say is it one-off? I can't say yes or no. So  
6 the answer is: Based on the information you presented  
7 as far as testing goes, that certainly supports there  
8 were.

9           My opinion is, until you have done the  
10 investigation to the level I'd expected, it's  
11 possible.

12          Q. Do you have any opinion to a probability what  
13 the kind of investigation you think should have been  
14 done would have revealed?

15          A. Yeah. Number 1, it would have identified  
16 compressability. It would have identified  
17 flowability. It would have identified any changes in  
18 morphology. And these things are all in the  
19 literature and they are in your citations -- the  
20 citations I gave you. And not only that, it's also  
21 stuff that I customarily do.

22           What I would be looking for is any change in  
23 crystal structure. Even at the low dose we have, it  
24 can make these things more sticky or less sticky; it  
25 can cause more flow or less flow; and things that can

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1 happen in the background without your knowledge.

2 Okay?

3 Q. But as far as I understand it, and you have  
4 certain batch records that you looked at and you have  
5 other batch records available on the plaintiffs'  
6 lawyers' website of documents; correct?

7 A. Uh-huh.

8 Q. Yes?

9 A. That's correct.

10 Q. Mark doesn't understand um-um and uh-huh.

11 A. Yes, yes.

12 Q. Okay? But you didn't see -- you don't talk  
13 about in your report problems with extra-thick tablets  
14 in any other batches before or after 70924; right?

15 A. That's correct.

16 Q. So it's conceivable that a good, solid  
17 investigation would have revealed that they just left  
18 some start-up tablets in the deduster and that it was  
19 not a common problem to other batches; right?

20 MR. MILLER: Object to form.

21 A. If I -- I would -- I would agree, had I not  
22 looked at the quality of the deduster that Actavis  
23 uses. It is not likely that that is the case.

24 I agree there that's a credible excuse, Matt;  
25 but after my inspection, it's not likely.

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1 Q. Well, a good solid investigation could have  
2 found a root cause that was just a one-off; right?

3 A. Usually -- My point exactly. A one-off, if  
4 you agree that it's a one-off and everybody says it's  
5 okay and you move on, is fine, as long as you are  
6 absolutely certain it's a one-off.

7 Q. It's pretty hard to always be absolutely  
8 certain; isn't it?

9 A. Yes. Uh-huh.

10 Q. You said yes; right?

11 A. Yes.

12 Q. Have there been many times in your work in  
13 the pharmaceutical industry where you didn't come to a  
14 root cause?

15 A. Yes.

16 Q. Okay. Page 11.

17 A. Uh-huh.

18 Q. Fifth paragraph.

19 A. "The attributes"?

20 Q. Yes.

21 A. Uh-huh.

22 Q. The second sentence I don't understand.

23 A. Okay.

24 Q. "Tablet weight assures the proper level of  
25 API is contained within each tablet."

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1                   Do you see that?

2           A.    Yes, sir.

3           Q.    Is that true?

4           A.    "The tablet weight assures the proper level  
5 of API is contained in each tablet."

6                   That is true because the blend feed stock is  
7 uniform.

8           Q.    Okay.

9           A.    Right?

10          Q.    I mean you could have a proper weight tablet  
11 that's 100 percent excipients; right?

12          A.    Exactly the point, Matt. And that -- but  
13 that speaks to the blend, not the tablet.

14          Q.    All right. And presumably that's why you do  
15 finished product testing?

16          A.    Yes, but remember: One of the things we as  
17 an industry suffer from is end-use testing. End-use  
18 testing is not adequate in most cases to control the  
19 process.

20          Q.    Did you ever see any place where FDA cited or  
21 warned Actavis, or even Amide, for the use of Stokes'  
22 BB2 tablet presses.

23          A.    I don't recall seeing stuff about that.

24          Q.    The fact that --

25          A.    There was a question about their

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1 qualification, but not the use as I recall it.

2 Q. Have you ever seen anything in the material  
3 that says that the Stokes machines weren't qualified?

4 A. I'd have to actually -- to be -- I vaguely  
5 remember seeing something about qualification.

6 Whether it was the Stokes or not, Matt, I have to say  
7 I don't know. I'd have to go and look.

8 MR. MILLER: Well, you can take your time and  
9 look if you need to.

10 Q. Can you answer while you look?

11 MR. MILLER: No.

12 Q. Can you multi task?

13 MR. MILLER: No.

14 Q. Let me ask you a couple of questions before  
15 you look.

16 A. Yeah.

17 Q. FDA was well aware that my client was using  
18 Stokes BB2 tablet presses from the ANDA and every  
19 batch record; correct?

20 A. Absolutely. Batch presses are noted in the  
21 ANDA, yes.

22 Q. Even after Batch 70924, did FDA ever give a  
23 483 or warning letter about the use of Stokes BB2  
24 tablet presses?

25 A. No, I don't recall that.

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1           And, again, my only question was whether or  
2 not they did their homework on qualifying. Okay?  
3 That's it.

4           Q. Is there any CFR or any other regulations  
5 requiring the use of tabletting equipment with weight  
6 controls?

7           A. Again, CFRs are meant to give equipment --  
8 excuse me -- to given industry guidance, but not to  
9 mandate how they run their business. So there is no  
10 mandatory requirement that they run an instrumented  
11 tablet press.

12          Q. Okay. Have you ever seen any evidence that  
13 Digitek was cross contaminated with any other product?

14          A. Absolutely not.

15          Q. When there is equipment, tabletting equipment  
16 with weight controls, do they typically weigh all the  
17 tablets, or is it random sampling?

18          A. Well, Matt, tablets -- with a weight control  
19 system does not weigh tablets. What it weighs is the  
20 force applied to form the tablets. So what it does is  
21 it monitors the pressure in a finite environment.

22           To clarify, it measures every one, every  
23 tablet is measured. It's not necessarily weighed.  
24 It's indirect. Okay?

25          Q. Let's go to Page 13 of your report.

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1 A. Yes, sir.

2 Q. It says, "The data for digoxin manufacture  
3 that we reviewed show a lack of appreciation of the  
4 dangers of this compound."

5 My client has made billions of digoxin  
6 tablets. How many have you been involved in making?

7 A. I never made digoxin, sir.

8 Q. So what is the basis for your statement that  
9 my client shows a lack of appreciation for the dangers  
10 of the compoundinig?

11 A. It seems to me that my involvement with  
12 highly potent products in the past, which is more  
13 in -- highly potent means low dose, as taken here;  
14 that more care is given to maintaining their weight,  
15 assuring homogeneity. That's all. That's what I'm  
16 trying to say.

17 I was comparing it to people making highly  
18 potent compounds.

19 Q. Well, so far as weight is concerned, did you  
20 find evidence in the material that you reviewed that  
21 there were batches which made it to market that had  
22 weight issues?

23 A. Not based on the run -- the run sheets I  
24 looked at, no.

25 Q. Okay.

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1       A.    But, again, understand that the weight of the  
2 tablet is not an indicator of its uniformity.

3       Q.    I know.   But you just used weight as an  
4 example?

5       A.    True, but weight is in fact only an indicator  
6 of the dosage form.   We get right back to the fact  
7 that the dosage form itself has to be uniform, and  
8 what I'm trying to be clear about is:   You could have  
9 a uniformly weight -- a uniform weight batch, tablets  
10 right down the middle, but the blend that goes to feed  
11 that material has to be uniform, so that each aliquot  
12 is the same.

13           I'm sorry, if I misunderstood -- if I  
14 misunderstood.

15       Q.    And you are basing that on the less than a  
16 handful of blend investigations that you saw in these  
17 materials.   Is that right?

18           MR. MILLER:   Object to form.

19       A.    Here again, in my profession, usually we are  
20 brought in, we are not given all of the details.   The  
21 answer (sic) is:   Do we see a potential problem?   And  
22 based on the information I was presented, the answer  
23 is:   Yeah.

24           I looked for the usual candidates that lead  
25 to problems, and they were all there.   Lack of

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1 investigation, lack of understanding of the API, you  
2 know, in general.

3 There's a lot of investigations, Matt, and  
4 there's not a lot on the side -- you know, not a lot  
5 that focus on the things that I would have looked at.

6 Q. What do you mean in the next paragraph by  
7 "The firm lacks the fundamental understanding of the  
8 need to define the requirements of the product to be  
9 manufactured and take actions within their supply  
10 chain"?

11 A. That gets back to my API point. If, in fact,  
12 they didn't look at the API, how would they be able to  
13 feed back into their supply chain that they are  
14 getting the necessary material for the necessary  
15 functionality purpose. That's all I'm saying.

16 Q. Have you ever seen any FDA 483 or warning  
17 letter indicating that Actavis did not pay adequate  
18 attention to its API -- raw API?

19 A. I don't think that they were cited  
20 specifically on that, no.

21 Q. Do you have any information at all that shows  
22 that active pharmaceutical ingredient that was of  
23 inappropriate potency or purity was used in Digitek?

24 A. No.

25 Q. Does -- At Page 14 --

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1 A. Yes.

2 Q. -- you are talking about V-shaped blenders  
3 and double-cone blenders --

4 A. Right.

5 Q. -- being of different geometry; right?

6 A. Right, uh-huh.

7 Q. That's a yes?

8 A. Yes, sir.

9 Q. Does FDA actually consider them part of the  
10 same family?

11 A. Yes, they do.

12 Q. What do the SUPAC guidelines say about the  
13 use of V-shaped and double-cone blenders in the  
14 same --

15 A. They're in the same class, but different sub  
16 classes.

17 Q. Does SUPAC specifically say not to use them  
18 in the same drug production?

19 A. It doesn't give you that guidance. When we  
20 put SUPAC together, we dealt with that question  
21 specifically to give industry flexibility, but it  
22 requires that the owner of the firm assure that that's  
23 done properly.

24 Q. So the bottom line is: My client's use of  
25 this blender configuration doesn't violate any --

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1 A. Any regulation.

2 Q. -- regulation or guidance from SUPAC; right?

3 A. No, sir.

4 Q. Now, I've asked you a lot of questions today  
5 about whether you had evidence of out-of-spec Digitek  
6 making it to the hands of consumers. I don't need to  
7 rehash that.

8 But as we've gone through that, when I've  
9 been asking about out-of-spec tablets getting to  
10 consumers, what have you understood that to mean?

11 A. My understanding was out-of-spec tablets  
12 getting to consumers -- I've taken that simply from  
13 the analytical perspective. Okay? In other words,  
14 you have a set of specs and you test it. Right?

15 Q. Okay. Do the analytical specs include weight  
16 and thickness?

17 A. I believe those are in the testing monograph.

18 Q. And the testing monograph includes the range  
19 for the active pharmaceutical ingredient; right?

20 A. That's correct.

21 Q. All right. Anywhere in your report, did you  
22 say that tablets, either extra thick or outside the  
23 USP's active pharmaceutical ingredient specifications  
24 made it to the hands of consumers?

25 A. No, sir, I didn't make that statement.

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1                   MR. MORIARTY: Adam, how much time left do we  
2 have on the tape?

3                   THE VIDEOGRAPHER: We have I'd say a full 40  
4 minutes left.

5                   MR. MORIARTY: Okay. Let's just take a --

6                   Do you have questions that you know of right  
7 now?

8                   MS. CARTER: One or two.

9                   MR. MORIARTY: Let's take a five or ten-minute  
10 break. Let me go through all my notes with Ms.  
11 Downie and we will see where we are and be in a  
12 position to wrap this up. Okay?

13                  MR. MILLER: Okay.

14                  THE VIDEOGRAPHER: Please stand by. We are  
15 going off the record. The time is 3:48 p.m.

16                  (A recess is taken.)

17

18 CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

19                  THE VIDEOGRAPHER: We are back on the record.

20                  The time is 4:04 p.m.

21                  Q. Dr. Somma, I have a couple exhibits that I  
22 hadn't asked you about yet. I'm anxious to lighten my  
23 load.

24                  This is Exhibit 9. It's MOI145.

25                  You know what an MOI is; don't you?

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1 A. Yes, sir.  
2 Q. Method operating instruction?  
3 A. Yes, sir.  
4 Q. Have you seen this document?  
5 A. I have seen it, yes, sir.  
6 Q. I didn't notice any criticisms --  
7 A. No.  
8 Q. -- in your report about MOI145?  
9 A. No, sir.  
10 Q. You don't have any criticisms of it?  
11 A. No, sir.  
12 Q. This is Exhibit -- it's actually Plaintiffs'  
13 Exhibit 159. Have you seen this document before?  
14 A. Yes, sir.  
15 Q. This is a blend failure investigation?  
16 A. Uh-huh.  
17 Q. Is that a yes?  
18 A. Yes, sir.  
19 Q. Is this one of the documents you were relying  
20 on for your opinions about the blend issues in this  
21 situation?  
22 A. Yes, sir.  
23 Q. And lastly, this is Exhibit 288. And I'm  
24 sorry, I can't tell you whether that's Defense or  
25 Plaintiff's Exhibit 288, but it's 288.

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1 MR. MILLER: It's plaintiffs'.

2 MR. MORIARTY: Is it? Oh, it says,

3 "Plaintiffs" on it. That's a pretty good hint.

4 (A discussion is held off the record.)

5 Q. Have you seen this document before?

6 A. I've seen test reports of blend assay, not  
7 this specific one.

8 Q. Okay. Is this an investigation of a --  
9 either a planned or an unplanned deviation in blend  
10 uniformity? And I see in here some planned  
11 deviations, and then in the back I see an out-of-spec  
12 investigation.

13 Do you know what this document is?

14 A. I haven't looked through it yet.

15 Q. Did you rely on it in forming opinions in  
16 this case?

17 A. No, sir.

18 Q. All right.

19 A. Not that I recall.

20 Q. Okay. Then I won't ask you about it.

21 A. Okay.

22 Q. Does FDA have a good scientific reason to  
23 take 484 samples and test them?

24 MR. MILLER: Object to form.

25 A. That's a good question -- that's a good

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1 question. I don't think I know the answer. From a  
2 scientific standpoint it's to confirm that you've done  
3 what they told you to do. Isn't that called -- isn't  
4 that part of vigilance, follow-up, I guess?

5 Q. If either Actavis' finished product testing  
6 or any testing done by Celsis Labs or any 484 sampling  
7 and testing done by FDA had been out of specification  
8 regarding Digitek, do you think that would have been  
9 important to your opinions?

10 A. Yes.

11 Q. On the flip side of that coin, isn't the  
12 absence of out-of-spec testing by all three of those  
13 entities unfinished product testing significant?

14 MR. MILLER: Object to form.

15 MS. CARTER: Object to form.

16 (A discussion is held off the record.)

17 A. I think it's significant.

18 Q. Did you perceive your role in this  
19 consultation to be to assess whether there were  
20 potential problems with the production of Digitek?

21 A. If there was a -- a problem that was not  
22 identified, perhaps; something that was not seen  
23 before.

24 Q. In other words, a potential problem?

25 A. A potential problem.

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1 Q. And "potential" is really "possibility"; is  
2 it not?

3 MR. MILLER: Object to form.

4 A. I guess I'd have to put it in that category  
5 of possible, yeah.

6 Q. And the existence of a potential problem does  
7 not always mean that there is an actual problem. Is  
8 that right?

9 A. Unless you go about answering the question in  
10 the investigation; then you can't say if it's  
11 potential or not. But that's how I do business, how I  
12 do my job.

13 Q. And just to make sure I understand your  
14 thoughts on this case completely, are you saying that  
15 Actavis was, in fact, producing Digitek outside the  
16 specifications, and it's just a sheer coincidence that  
17 none of it was detected by Actavis, FDA or Celsis or  
18 pharmacists?

19 MR. MILLER: Object to form.

20 A. I would say yes.

21 Q. What's the scientific basis for you to say  
22 that?

23 A. Because without identifying as these issues  
24 myself, the potential with the blend, the observations  
25 I made with the blend, that they -- in here; the

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1 observations with even the heavyweight tablets or  
2 whatever we call them, double-thick tablets, I am not  
3 thoroughly convinced that the investigation into the  
4 root cause uncovered all the potential issues. To my  
5 satisfaction.

6 Q. Are you done with your answer?

7 A. Yes, sir.

8 MR. MORIARTY: Can you read that back, please,  
9 from the "I'm not thoroughly convinced" part.

10 (The answer is read.)

11 Q. Would you agree with me that the fact that  
12 Russ Somma is not thoroughly convinced that the  
13 investigation uncovered all of the problems to your  
14 satisfaction does not mean that consumers actually  
15 received out-of-specification Digitek?

16 MR. MILLER: Object to form.

17 A. That I am not convinced, me? I am not  
18 convinced that they --

19 Let me have the question again, please.

20 I'm sorry, Matt.

21 (The question is read.).

22 A. Gee, I must be thick. I'm sorry.

23 Q. Okay. That's fine. If you don't understand  
24 it -- or it's late, it's late.

25 A. I'm a little thick. I'm sorry.

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1 Q. You told me --

2 A. Yeah.

3 Q. -- just a minute ago that you weren't  
4 thoroughly convinced that the investigation of 70924  
5 uncovered all the problems to your satisfaction?

6 A. Right.

7 Q. Correct?

8 A. That's correct.

9 Q. That's your opinion --

10 A. That's my opinion.

11 Q. Russell Somma?

12 A. Right.

13 Q. Correct?

14 A. That's right.

15 Q. Just because you are not thoroughly convinced  
16 that that investigation uncovered all the problems to  
17 your satisfaction does not necessarily mean that  
18 consumers actually got Digitek that was outside the  
19 specifications. Isn't that correct?

20 MR. MILLER: Object to form.

21 A. Everything I've looked at Matt, you know, for  
22 me to agree with you, I would have to be convinced  
23 that this information is there, and I'm not. I'm  
24 really not. If this was Novartis and you asked me  
25 that and you were -- you were my superior, my

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1 recommendation is no, I'm not convinced and,  
2 therefore, I'm not comfortable with the situation.  
3 That's just the way I am.

4 Q. Well, are you asking me to prove to you that  
5 there weren't defective tablets in the hands of  
6 consumers?

7 MR. MILLER: Object to form.

8 A. No, I'm -- I want to see information that was  
9 done in a rigorous enough fashion that I am convinced.  
10 Sorry.

11 Q. All right. That's not my question.

12 A. I'm sorry.

13 Q. Okay. The purpose of this lawsuit is not for  
14 you to be convinced about the rigors of this  
15 investigation.

16 A. Okay.

17 Q. All right? I thought I'd asked this many  
18 times before today, and I don't want to rehash it and  
19 go on and on and on.

20 I haven't heard you say anything today where  
21 you say to a probability that you have some scientific  
22 proof that consumers got out-of-specification Digitek.

23 MR. MILLER: Object to form. If there's a  
24 question.

25 Q. Are you changing your opinion in that regard?

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1 A. No, sir.

2 Q. Okay. So do you see what I'm trying to drive  
3 at here? Your level of -- your not being thoroughly  
4 convinced that the investigation revealed problems  
5 with that one batch does not prove that there was  
6 out-of-spec Digitek in the hands of consumers; does  
7 it?

8 MR. MILLER: Object to form.

9 A. And, again, what I have to point to is that  
10 all of the parts have to move and have to work  
11 properly. And there's certainly information that says  
12 in general, the quality systems here were not  
13 functioning properly.

14 Q. Give me all the affirmative, scientific  
15 evidence that you have that any consumers got  
16 out-of-specification Digitek in their prescription  
17 vials?

18 A. And, again, if all we rely upon is the  
19 specifications, we wouldn't be having this  
20 conversation. The answer is: There's got to be  
21 another dimension to it, and that dimension is the way  
22 in which they manufactured the product, and that is  
23 the point I keep trying to make.

24 I haven't seen anything beyond: They meet  
25 specs. If you live by the specs, you die by the

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1 specs. It's as simple as that. That's a  
2 narrow-minded approach. And I agree with you, they  
3 all met spec.

4 MR. MORIARTY: I'm going to pass the witness to  
5 Ms. Downie.

6

7 CROSS EXAMINATION BY MS. DOWNIE:

8 Q. Dr. Somma, I have just a few questions for  
9 you.

10 You testified earlier today that you were  
11 contacted initially by Spyglass, Mr. Kenny's  
12 organization. Is that correct?

13 A. That's correct.

14 Q. And when were you first contacted by Mr.  
15 Kenney?

16 A. In March.

17 Q. How many times have you spoken with him  
18 regarding this litigation?

19 A. Two -- three times.

20 Q. And when he first contacted you, what did he  
21 tell you he expected your role to be in this  
22 litigation?

23 A. To be the technical opinion.

24 Q. And did he provide to you details regarding  
25 what the litigation was about?

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1       A. Other than the fact that an oversized tablet  
2 was distributed, no. That's all I understood.

3       Q. Do you recall any other specifics of that  
4 conversation?

5       A. The conversation revolved around: Had I seen  
6 problems like this before, what is my opinion. That's  
7 about it.

8       Q. And had you seen problems like this before?

9       A. Yes, the same that I outlined before.

10      Q. Okay. And you said you had spoken to him  
11 about two or three times?

12      A. Right.

13      Q. Do you recall the substance of your  
14 conversations subsequently?

15      A. The next one was we met on Crivella to talk  
16 about the information, and then we decided -- you  
17 know, we wanted to make sure that what I focused on as  
18 far as content was something -- was nothing that he  
19 had -- that he had focused on, I guess what I'm trying  
20 to say; to understand what our approach was going to  
21 be.

22      Q. Why was it important that your opinions not  
23 overlap?

24      A. I wanted to make -- I wasn't going to produce  
25 something that was -- in other words, as I understood

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1 it, I told you what my limitations are. I'm not a  
2 regulatory person. I'm not a compliance person. So my  
3 point was: I looked at the technical dimension. That  
4 was it.

5 Q. And what do you understand his role to be?

6 A. My understanding is, Mark is quality  
7 assurance.

8 Q. Quality assurance?

9 A. That's my understanding.

10 Q. Have you taken a look at his report?

11 A. No, sir.

12 No, ma'am. Sorry.

13 Q. That's okay. It's been a long day. I won't  
14 take offense.

15 Have you discussed with him what his opinions  
16 are?

17 A. No, ma'am.

18 Q. You just discussed what the scope of his  
19 opinions would be?

20 A. I discussed what -- where he would come down  
21 as to what his definitions and his assessment would  
22 be; not the scope.

23 Q. What did he tell you his definitions of --

24 A. Quality assurance, quality systems; you know,  
25 these kind of things that lead up to that.

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1      Customarily when we do a technical investigation, we  
2      don't go down and drill through training manuals and  
3      SOPs. Okay?

4            Q.     How long -- Or how many times have you worked  
5      with Mr. Kenney in investigations --

6            A.     Never before.

7            Q.     -- before consulting --

8            A.     Never before.

9                Oh, I'm sorry. Never before.

10          Q.     And are you -- have you been retained by  
11     Spyglass or are you retained by the plaintiffs'  
12     counsel in litigation?

13          A.     I work for -- I work for Motley, Rice,  
14     plaintiffs' counsel.

15          Q.     Okay. Were you given any kind of consulting  
16     fee or did you pay any consulting fee to Spyglass?

17          A.     No, I did not.

18          Q.     Okay.

19          A.     This was something, when -- when we first  
20     talked, this was -- this was sorted out between  
21     myself, Motley, Rice and Spyglass. And Motley, Rice  
22     gave us the direction and we were totally separate.

23          Q.     Other than Mr. Kenney, have you spoken to any  
24     other individuals regarding this litigation, other  
25     than of course plaintiffs' attorneys?

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1 A. Sal Romano, who works with Mark Kenny.

2 Q. And how many times have you spoken -- I'm  
3 going to say Sal, because I'm not sure of the last  
4 name.

5 A. Right, Romano.

6 Two times, as far as I recall.

7 Q. Two times. And what were your discussions  
8 with Mr. Romano?

9 A. The initial investigation -- the initial  
10 interview, if I had the background in tabletting.  
11 Okay? And the second time was when we trained on how  
12 to use Crivella.

13 Q. Remind me again what Crivella is?

14 A. Crivella is a database --

15 Q. Right.

16 A. -- that all of this stuff is on.

17 C-r-i-v-e-l-l-a.

18 Q. That's right. That's what you looked at the  
19 batch records on; is that correct?

20 A. That's where the batch records are.

21 Q. Why are the batch records important for you  
22 to review?

23 A. Batch records to me are the manner in which  
24 the company manages that part of the manufacturing.  
25 This is the hands-on approach that the operator does,

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1 it's his direction, and that's his personal interface.  
2 That's the human interface, in my opinion. It also is  
3 a reflection of all of the sum total knowledge from  
4 development to maturation, it's in the batch records.  
5 This is how you make it.

6 Q. And I believe it was your testimony earlier  
7 that you believe that Actavis should have reviewed the  
8 batch records before and after?

9 A. That's an opinion, yes.

10 Q. That's right. And you have only reviewed  
11 the batch record that occurred prior. Is that  
12 correct?

13 (A discussion is held off the record.)

14 A. As close as I can get.

15 MR. MILLER: Asked and answered.

16 (A discussion is held off the record.)

17 Q. How many times have you personally been  
18 involved in a visual inspection of the type that was  
19 conducted by Actavis?

20 A. Two times.

21 Q. When were those?

22 A. I would have been -- guessing now, early  
23 '80s, and these were primarily in a clinical dosage  
24 form area. But again --

25 Q. What were the context of those individual

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1 inspections, why were they being conducted?

2 A. In those particular cases, we were looking  
3 for capsules, if I recall. I think it was a cracked  
4 capsule.

5 Q. You were looking for cracked --

6 A. Cracked capsules.

7 Q. In both instances?

8 A. In one instance, I think. I think the other  
9 one what is I recall was a double debossed problem.  
10 It's kind of like a -- it's not a double thick, excuse  
11 me. It's sort of like an overwritten imprint. That  
12 was a total bust, by the way.

13 Most of my other have been systems,  
14 electronic systems.

15 Q. Okay.

16 MS. DOWNIE: I don't have any other questions.

17 Thank you.

18 MR. MORIARTY: I think I just have one more.

19

20 REDIRECT EXAMINATION BY MR. MORIARTY:

21 Q. In that private consulting engagement you had  
22 with the extra thick tablets, was anyone asked to  
23 prove whether thick tablets were -- actually got to  
24 consumers?

25 A. I believe it was reacting -- I think it was

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1 as a result of a field complaint. And, again, I  
2 didn't get deeply into that, but my understanding was  
3 a field complaint. Because there was subsequent  
4 regulatory action as I recall as a result.

5 Q. Is that what started the investigation?

6 A. I believe so.

7 Q. Okay. So the fact that there was a field  
8 complaint, do you know whether it was from a  
9 pharmacist or a consumer?

10 A. That I don't recall, Matt. I don't.

11 Q. All right. Well, a field complaint, was it  
12 pharmacist or consumer?

13 A. To be honest, Matt, I don't know. You know,  
14 because I realize that they can come in by various  
15 conduits. To be perfectly honest, I don't -- all I  
16 know is: We got a complaint.

17 In my business, if I got a complaint from the  
18 field. To me that means, well, somebody caught it  
19 outside the confines that you have control over.  
20 That's bad. Okay? That's how I took it. How it came  
21 in, Matt, I can't tell you. I don't know.

22 Q. It's bad, but it happens?

23 A. It happens.

24 MR. MORIARTY: All right. I don't have any  
25 other questions.

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1 MR. MILLER: I have a couple of questions.

2

3 RECROSS EXAMINATION BY MR. MILLER:

4 MR. MORIARTY: And, again, I object in general  
5 to you asking your own experts questions in my  
6 deposition. But go ahead.

7 MR. MILLER: Okay.

8 Q. Dr. Somma, do you have an opinion to a  
9 reasonable degree of probability that Actavis released  
10 the product Digitek outside of specification with  
11 regard to thickness specifications over the course of  
12 time that the recalled products were manufactured?

13 A. Yes.

14 Q. Do you have an opinion to a reasonable degree  
15 of probability that out-of-specification Digitek  
16 tablets were released during the time of manufacturing  
17 for the recall product that were out of specification  
18 for blend uniformity specifications?

19 A. Well, that's certainly a tough one, but the  
20 answer is, again, based on what I looked at because,  
21 you know, the blend question itself in my opinion has  
22 not been resolved to an adequate level, I would have  
23 to say yes.

24 Q. We went over the opinions in your expert  
25 report. Other than the information that you had

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1      corrected --

2            A.     Right.

3            Q.     -- that you had picked up yesterday, has  
4       anything been shown to you or said today that alters  
5       any of the opinions that you have in your report?

6            A.     No. We talked about the sample frequency. I  
7       was wrong there. Okay?

8            Q.     Right. We covered that.

9            A.     Okay. Other than the fact that I obviously  
10       made that one mistake, these are still -- these  
11       bullets are still -- are what I've put down and these  
12       are my opinions based on what I've read.

13           Q.     Do you hold these opinions to a reasonable  
14       degree of probability?

15           A.     Within the same probability that we have been  
16       discussing today, yeah.

17           MR. MILLER: I have no further questions.

18           MR. MORIARTY: Okay. I have more now.

19

20 RE-DIRECT EXAMINATION BY MR. MORIARTY:

21           Q.     Let me see if I can make sure I understand.

22           Mr. Miller asked you if you had an opinion to  
23       a reasonable probability about whether my client was  
24       releasing Digitek that was too thick over the course  
25       of the time of the recalled batches.

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1                   Do you remember that question he just asked  
2        you?

3           A.    Uh-huh.

4           Q.    How many batches?

5           A.    How many batches were recalled?

6           Q.    No. How many batches had extra-thick tablets  
7        that were released?

8           A.    I'm -- that I -- the probability of giving  
9        you that number, I don't know.

10          Q.    Which batch numbers? Which batch numbers had  
11        extra-thick tablets?

12          A.    I think -- I'm thinking about this that this  
13        had happened and gone undetected. In that case, how  
14        would I know the batch numbers?

15          Q.    Well, how would you know it happened and went  
16        undetected? What's that based on?

17          A.    Simply -- simply the lack of rigor that was  
18        conducted and the way they analyzed the problem.

19          Q.    On 70924?

20                   MR. MILLER: Object to form.

21          Q.    That's the batch you said had no rigor;  
22        right?

23          A.    Yes

24                   MR. MILLER: Object to form.

25          Q.    Okay. That was December of 2007; correct?

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1 A. Uh-huh, uh-huh, yes, it is.

2 Q. So tell me what basis you have whatsoever to  
3 say that out-of-spec tablets that were too thick ever  
4 left Actavis's premises before that even happened in  
5 2007?

6 A. Well, there was the one report on the 2000 --  
7 in 2004; right? For a thick tablet.

8 Q. Yeah.

9 A. Okay. Right?

10 Q. Okay. Anything else?

11 A. No.

12 Q. So out of the billions that were made, we  
13 have one tablet that actually made it to a pharmacist  
14 out of billions; correct?

15 A. Uh-huh.

16 Q. Yes?

17 A. That's correct, sir.

18 Q. And that's your basis for an opinion to a  
19 scientific probability that this was an ongoing  
20 problem?

21 MR. MILLER: Object to form. It misstates  
22 previous testimony.

23 A. Again --

24 Q. Yes or no?

25 MR. MILLER: No.

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1 Q. Is that your basis to say that this was an  
2 ongoing problem?

3 A. Yes.

4 Q. All right. So I want to get back.

5 What batches and how many batches, give me  
6 the numbers, give me how many?

7 MR. MILLER: Objection. Asked and answered.

8 Q. Is the answer: You can't do it?

9 MR. MILLER: Objection.

10 MR. MORIARTY: Well, if it was answered, that  
11 was the answer I heard.

12 MR. MILLER: Well, you heard wrong. That's  
13 not what he said.

14 MR. MORIARTY: Okay.

15 MR. MILLER: He said he didn't know.

16 Q. Got any field complaints you can show me?

17 A. No, sir.

18 Q. Got any test results you can show me for  
19 thickness or weight?

20 A. Nothing other than what you showed me.

21 Q. Do you have anything scientific that you can  
22 show me besides the 2004 incident, between then and  
23 the end of November 2007, anything at all?

24 MR. MILLER: Objection. Asked and answered.

25 A. Again, everything I've looked at -- All

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1 right? -- from a scientific basis indicates that  
2 there is a product that was released, it was within  
3 the requirements. Does that mean all of the -- there  
4 is nothing else going on?

5 And, again, this is simply my opinion. And  
6 in my opinion, without more investigation or better  
7 rigor than that, I can't tell you if it got out there.  
8 Is the evidence there? There is one tablet in '04 and  
9 that was it.

10 Q. So it is your opinion, but when I ask you for  
11 a scientific proof of the opinion, you can't point to  
12 a document in the materials you've looked at. Is that  
13 right?

14 MR. MILLER: Object to form.

15 A. There was nothing in here that clearly drew  
16 that conclusion, correct.

17 Q. Okay. Then the next opinion you had that Mr.  
18 Miller asked you about was essentially the same  
19 question: Did you have a reason -- an opinion to a  
20 reasonable probability that there was something about  
21 out-of-spec blend uniformity that made it to end  
22 release.

23 Do you remember that question?

24 A. Yes.

25 Q. Okay. Let's get -- let's get accurate about

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1 what happens. If, in fact, there is a blend  
2 uniformity that is truly out of spec, it leads to the  
3 possibility that there will be more active  
4 pharmaceutical ingredient in some part of the batch  
5 and less in the other; correct?

6 A. That's correct.

7 Q. And a batch is not released that way; it is  
8 tabletted --

9 A. That's right.

10 Q. -- and then it goes out; correct?

11 So the theory would be that some tablets in  
12 that particular batch might have too much and others  
13 might have too little of the active pharmaceutical  
14 ingredient; correct?

15 A. That's correct.

16 Q. All right. Now, I don't want to plow old  
17 ground over and over, because I've asked you this  
18 before. But can you identify any field complaints  
19 where that was documented to have occurred?

20 MR. MILLER: Objection, asked and answered.

21 Q. In the material you reviewed.

22 A. Right. No.

23 Q. Can you document any test results to indicate  
24 that that actually occurred?

25 A. Not that I recall.

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1 Q. Can you identify any batch by number where  
2 that occurred?

3 MR. MILLER: Objection. Asked and answered.

4 A. I think the answer was no for that.

5 Q. Can you identify how many batches in which  
6 that occurred?

7 MR. MILLER: Objection, asked and answered.

8 A. Again, that -- that gets into that point that  
9 I really can't make an estimate.

10 Q. All right. And the last question is: If  
11 that ever occurred, you can't quantify how many  
12 tablets were high or low; right?

13 A. Exactly. As we discussed.

14 MR. MILLER: Objection. Asked and answered.

15 A. And I apologize.

16 MR. MILLER: We are done.

17 THE VIDEOGRAPHER: Please stand by.

18 MR. MORIARTY: Well, stay on mark's record.  
19 You can go off the video.

20 THE VIDEOGRAPHER: Stand by. We are going off  
21 the record. The time is 4:36 p.m. This is the end  
22 of Tape Number 5.

23 MR. MORIARTY: Exhibit 51A is the little white  
24 box of thumb drives. Do you have any problem with  
25 me taking this in my briefcase back to my office?



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1 C E R T I F I C A T E

2  
3  
4 I, MARK SCHAFFER, a Shorthand Reporter and  
5 Notary Public of the States of New York and New  
6 Jersey, do hereby certify that prior to the  
7 commencement of the examination the witness was sworn  
8 by me to testify to the truth, the whole truth and  
9 nothing but the truth.

10 I do further certify that the foregoing is a  
11 true and accurate transcript of the testimony as taken  
12 stenographically by and before me at the time, place  
13 and on the date hereinbefore set forth.

14 I do further certify that I am neither of  
15 counsel nor attorney for any party in this action and  
16 that I am not interested in the event nor outcome of  
17 this litigation.

18

19

20

21

MARK SCHAFFER, C.S.R.

22

23 New Jersey C.S.R. License Number XI00794  
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2 Plaintiffs, )  
3 vs. )  
4 ACTAVIS GROUP HF, et al., )  
5 Defendants. )  
-----X

6  
7  
8  
9  
10

11 I have read the foregoing transcript and found  
12 it to be a truthful and accurate representation of the  
13 testimony I gave in connection with the captioned  
14 matter on \_\_\_\_\_.

15  
16  
17

18 \_\_\_\_\_ RUSSELL SOMMA, PhD  
19

20  
21 The State of:  
County of:

22  
23

24 Sworn and subscribed before me  
this day of , 2010  
25 My commission expires:

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2

3 Please list any correction with the  
corresponding page and line numbers.

4

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